JUN - 2 2003

DENKA SEIKEN CO.,LTD.
3-4-2, Nihonbashi kayabacho, Chuo-ku, Tokyo, Japan 103-0025

I. 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is: K030545

(A) (1) Submitter's name: Denka Seiken Co., Ltd.

Submitter's address: 3-4-2, Nihonbashi kayabacho,
Chuo-ku
Tokyo, Japan 103-0025

Submitter's telephone number: (03) 3669-9421

Contact Person: Mr. Toshimi Matsunaga
Manager
Regulatory & Pharmaceutical Affairs

Date Summary Prepared: February 17, 2003

(2) Trade or proprietary device name: CRP-Latex (II)X2 SEIKEN Assay Kit
Common or usual name: Latex-enhanced turbidimetric in vitro immunoassay for determination of C-reactive protein
Classification Name: C-reactive protein immunological test system
Panel: Immunology
Class: II

(3) Legally marketed predicate device: N High Sensitivity CRP Assay
[Dade Behring Inc,](K991385).

(4) Subject device description:

The CRP-Latex (II)X2 SEIKEN Assay Kit is a latex *in vitro* diagnostic immunoassay for the quantitative determination of C-reactive protein in human serum and in heparinized and EDTA-plasma. Antigen in the sample bonds to the specific anti-CRP antibody, which has been adsorbed to latex particles, and agglutinates. The agglutination is detected as an absorbance change when read on an automated chemistry analyzer (the Hitachi 917 was used for these studies), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

(5) Subject device intended use:

The CRP-Latex (II)X2 SEIKEN Assay kit is an in vitro diagnostic test for the quantitative determination of C-reactive protein in human serum and lithium heparin or EDTA plasma samples by immunoturbidimetry. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury and inflammatory disorders.

(6) Performance data:

The CRP-Latex (II)X2 SEIKEN Assay and the predicate device, N High Sensitivity CRP Assay have only minor difference that do not affect the performance, safety or effectiveness of the measurement.

Comparative performance studies conducted on 451 donor samples yielded a high correlation coefficient upon comparison of the CRP-Latex (II)X2 SEIKEN and the predicate device, N High Sensitivity CRP. The correlation coefficient r = 0.999; slope = 1.012, y intercept = 0.005 (Least squares); slope = 1.053, y intercept = -0.004 (Passing/Bablock).

Precision studies, both within run and between day studies, were performed using three levels of control material. % CV for Level 1 did not exceed 7.0%; for Level 2, % CV did not exceed 3.4%; and for Level 3, % CV did not exceed 1.3%.

These findings serve to demonstrate that the performance of the CRP-Latex (II)X2 SEIKEN Assay kit is substantially equivalent to the predicate device, N High Sensitivity CRP (Dade Behring).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Toshimi Matsunaga
Manager Regulatory & Pharmaceutical Affairs
Denka Seiken Co., Limited
1-2-2 Minamihoncho, Gosen City
Niigata, Japan 959-1695

JUN - 2 2003

Re: k030545
Trade/Device Name: CRP-Latex (II)X2 SEIKEN Assay Kit
Regulation Number: 21 CFR § 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: II
Product Code: DKC
Dated: April 30, 2003
Received: May 5, 2003

Dear Mr. Matsunaga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): _____

Device Name: CRP-Latex (II)X2 SEIKEN Assay Kit

Indications for Use:

The CRP-Latex (II)X2 SEIKEN Assay kit is an in vitro diagnostic test for the quantitative determination of C-reactive protein in human serum and lithium heparin or EDTA plasma samples by immunoturbidimetry. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury and inflammatory disorders.

(Please do not write below this line—continue on another page if needed)

* * * * * * * * * *

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

J P Reeves for S. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K030545